REMARKS

Introduction

Claims 15-17, 22-23, 27-30 are pending. Claims 15 and 30 have been amended. Applicant notes that the markings made herein show the changes being made in comparison to the previously filed Response to Office Action which was filed on October 28, 2008.

Support for these amendments can be found throughout the specification, for example, in paragraphs [0019], [0026]-[0027], and in the original claims. No new matter has been added.

Claims 1-14, 18-21, and 24-26 have been cancelled without prejudice to the subject matter disclosed therein. Applicant expressly reserves the right to pursue the subject matter of the cancelled claims in this application or in another application.

Telephone conversation with Examiner

Applicant thanks the Examiner for the courtesy of discussing the timing for filing this Supplemental Amendment during a telephone conversation of February 9, 2009.

Rejection under 35 U.S.C. §103

The Examiner has rejected claims 15-17 and 22-29 under 35 U.S.C. §103(a) as allegedly being obvious in view of the five references cited in the Office Action. Specifically, the Examiner maintains that the claims are obvious over Pradalier et al., in view of Ball et al., Ćirković et al., Malley, and Marx. See Office Action at pg. 3 for full citations. Applicant traverses.

These documents do not disclose or fairly suggest all the features of the claims. The amended claims are directed to a pharmaceutical composition for sublingual, buccal or enteric administration comprising one or more peptides having a molecular weight of less than 10 kDa obtainable by hydrolysis with chymotrypsin or any other protease of an antigenic structure which induces graft rejection, allergic reaction or autoimmune disease, said antigenic structure being a

protein. After amendment herein, claim 15 also requires that the peptides are fragments of the protein.

Pradalier purports to disclose a preparation for sublingual administration comprising a 5 grass pollen extract. See page 821. The Examiner then cites Ball to demonstrate that grass pollen extract can be a peptide. As the Examiner recognizes, Pradalier in view of Ball does not, however, teach that the peptides have a molecular weight of less than 10 kDa. See Office Action at pg. 4.

To attempt to overcome this deficiency the Examiner relies on Malley. Malley discloses a structure of antigen B of Timothy grass pollen which consists of a flavanoid pigment (quercitin), a disaccharide and a polypeptide. See col. 1, ll. 8-12. It further discloses structures of antigen D_1, antigen D_2 and D_3 having peptide tails of about 5,000 or 2,500 Da. Malley also discloses that the antigenic determinant of the antigens is the quercitin, not the peptide. See col. 1, ll. 40-42. As a consequence, the antigenic structure taught in Malley is not a peptide but either a quercitin or a structure comprising quercitin, a disaccharide and a polypeptide. Amended claim 15, however, is directed to compositions having peptide fragments derived from a protein antigenic structure using for example, proteolytic hydrolysis. Malley does not disclose or fairly suggest the claimed compositions.

Ćirković does not remedy the deficiencies of Malley and Pradalier. Ćirković purports to disclose modifications of orchard grass pollen proteins to obtain "low molecular weight" allergoids. As the Examiner will appreciate, the term "low molecular weight" does not have a specific meaning in the art, it depends on the field and context within which the term has been used. Figure 1 of Ćirković shows that the most dominant peptide has a molecular weight of 43 kDa, in the modified M-Dg it seems to be slightly higher, in the modified S-Dg it seems to be about 35 kDa. Although Ćirković talks about "low molecular weight," the disclosed size appears to be at least three times the size defined in the claim. Thus, Ćirković does not provide sufficient motivation to use 10 kDa or less for the peptide.

The Examiner then cites Marx as teaching the use ATP as an adjuvant, but this document cannot cure the deficiencies of a combination of Pradalier with Ćirković and/or Malley and/or Ball.

Furthermore, amended claim 30 and dependent claim 29 are directed to compositions for enteric administration. The cited references do not disclose enteric administration of the claimed compositions. As disclosed in the application, enteric administration can involve protecting the active ingredient from absorption and/or degradation prior to entry into the intestine, which is distinct from the concerns of formulating a composition for buccal or sublingual administration. The Examiner has not cited a reference showing or fairly suggesting the features of new claim 30 or dependent claim 29.

For at least the above reasons, the pending claims are not obvious in view of the cited documents. Applicant respectfully requests that the Examiner withdraw the rejection under 103(a) and allow the claims to issue.

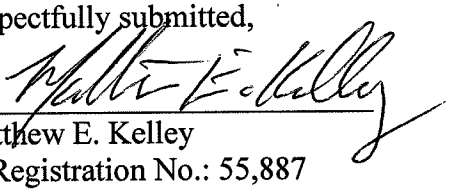
CONCLUSION

Applicant believes that the present application is in condition for allowance. Accordingly, Applicant requests that the Examiner issue a Notice of Allowance indicating the allowability of the claims and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR §1.17, including extension of time fees pursuant to 37 CFR §1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

Dated: February 10, 2009

Respectfully submitted,

By 

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